FILED by <u>LBC</u> D.C.

Oct 27, 2009

STEVEN M. LARIMORE CLERK U.S. DIST. CT. S.D. OF FLA. MIAMI

OF THE SOUTHERN DISTRICT OF FLORIDA WEST PALM BEACH DIVISION

Civil Action No.:_____

09-CIV-81584-MARRA/JOHNSON

LINDA K. SUVERISON, individually, and as Personal Representative of the Estate of Richard L. Suverison, Sr.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS, INC.,

A West Virginia corporation, f/k/a Mylan Bertek Pharmaceuticals, Inc.; ACTAVIS TOTOWA, LLC; ACTAVIS GROUP, hf.; And UDL LABORATORIES, INC.,

Defendants.

COMPLAINT

NOW comes the plaintiff, Linda K. Suverison, by and through undersigned counsel, and hereby commences her action individually and as Personal Representative of the Estate of Richard L. Suverison, against Mylan Pharmaceuticals, Inc., f/k/a Mylan Bertek Pharmaceuticals, Inc.; Actavis Totowa, LLC; Actavis Group, hf; and UDL Laboratories, Inc. (hereinafter collectively "Defendants" unless otherwise stated) for compensatory and punitive relief. Plaintiff makes the following allegations based upon her personal knowledge as to her own acts, and upon information and belief, as

well as upon her attorneys' investigative efforts as to Defendants' actions and misconduct, and allege as follows:

I. JURISDICTION AND VENUE

- 1. The Court has subject matter jurisdiction pursuant to 28 U.S.C. Section 1332 because the parties are citizens of different States and the matter in controversy exceeds the jurisdictional amount exclusive of interest and costs.
 - 2. Venue is proper under 28 U.S.C. Section 1332(a).

II. FACTS COMMON TO ALL COUNTS

- 3. Plaintiff has been appointed Personal Representative of the Estate of Richard L. Suverison, Sr., which is pending in the Circuit Court, Palm Beach County, Florida.
- 4. This is an action for Wrongful Death, pursuant to Florida's Wrongful Death statute, FS Section 768.19.
- 5. Linda K. Suverison is the surviving spouse of the decedent, and Richard L. Suverison, Jr. Is the surviving son of the decedent. During his lifetime, the decedent provided financial support to his son, Richard L. Suverison, Jr.
- 6. Accordingly, Plaintiff brings this action on behalf of herself, individually, and her son, Richard L. Suverison, Jr.

III. PARTIES

- 7. Plaintiff, Linda K. Suverison, is a citizen and resident of Palm Beach Lakes (Palm Beach County), Florida. Plaintiff, Linda K. Suverison, is the surviving spouse of Richard L. Suverison and the Personal Representative of the Estate of Richard L. Suverison, who resided in, and which Estate is being probated in, Palm Beach County, Florida.
- 8. Plaintiff, Linda K. Suverison, as Personal Representative of the Estate of Richard L. Suverison, states that Richard L. Suverison suffered bodily injuries and other damages as a result of his ingestion of recalled Digitek @ (Digoxin). Richard L. Suverison was prescribed, purchased and ingested Digitek @ (Digoxin) in Broward County, Florida.
- 9. Actavis Totowa, LLC is a New Jersey corporation. At all times relevant herein, Actavix Totowa, LLC was engaged in the business of manufacturing, marketing, promoting, testing, selling, and/or distributing Digitek @ (Digoxin).
- 10. Actavis Group, hf. Is a foreign corporation. At all times relevant herein, Actavis Group was engaged in the business of manufacturing, marketing, promoting, testing, selling, and/or distributing Digitek @ (Digoxin).
- 11. Mylan Pharmaceuticals, Inc. Is a West Virginia corporation with its principal place of business located in Morgantown, West Virginia. At all times relevant herein, Mylan Pharmaceuticals,

Inc. Was engaged in the business of marketing, promoting, selling an/or distributing Digitek @ (Digoxin).

- 12. Mylan Pharmaceuticals, Inc. Was formerly known as Mylan Bertek Pharmaceuticals, Inc., which was a Texas corporation. At all times relevant herein, they were engaged in the business of manufacturing, marketing, testing, promoting, selling and/or distributing Digitek @ (Digoxin).
- 13. UDL Laboratories, Inc. Is an Illinois corporation. At all times relevant herein, UDL Laboratories, Inc. Was engaged in the business of manufacturing, marketing, testing, promoting, selling and/or distributing Digitek @ (Digoxin).

IV. INTRODUCTION

- 14. Actavis Group, through its manufacturing division, Actavis Totowa, LLC, designed, researched, tested, and manufactured Digitek @ (Digoxin). Mylan Pharmaceuticals, Inc. Distributed Digitek @ (Digoxin) through its affiliates: Mylan Bertek Pharmaceuticals, Inc. And UDL Laboratories, Inc. Under the labels of Bertek and UDL. All defendants advertised, marketed, promoted and sold Digitek @ (Digoxin).
- 15. Digitek @ (Digoxin) is widely used in the treatment of various heart conditions including atrial fibrillation, atrial flutter and heart failure that cannot be controlled by other medications. The United States Food and Drug Administration (FDA)

approved the medication to be manufactured, distributed and sold with approved levels of active ingredient.

- 16. Digitek @ (Digoxin) was widely sold throughout the United States. Digitek @ (Digoxin) was a mass-marketed product throughout the United States. Numerous consumers have been similarly injured by Defendants' wrongful conduct.
- 17. Defendants were negligent in the design, testing, manufacturing, advertising, marketing, promotion, labeling, warnings given and sale of Digitek @ (Digoxin) because the medication was provided for use by the public with twice the approved level of active ingredient.
- 18. Digitek @ (Digoxin) has a narrow therapeutic index and, thus, has a limited margin between effectiveness and toxicity.
- 19. Ingestion of excess levels of the active ingredient in Digitek @ (Digoxin) beyond the level approved by the FDA can cause death and other health problems.
- 20. Upon information and belief, Defendants received at least eleven (11), and possibly more, complaints about significant adverse effects, including illnesses and injuries, from Digitek @ (Digoxin) since 2006.
- 21. Defendants have a history of releasing drug products for public consumption that have been adulterated.

- 22. Defendants have a history of failing to reliably establish the identity, strength, quality and purity of drug products they release for public consumption.
- 23. Defendants have a history of failing to adequately investigate and document out-of-specification test results on their drug products.
- 24. Defendants failed to adequately warn users of the defective drug of its unreasonably dangerous characteristics due to the excess levels of active ingredient the drug contained.
- 25. Richard L. Suverison suffered from congestive heart failure and was prescribed Digitek @ (Digoxin) by his physician.
- 26. As a result of Richard L. Suverison's ingestion of Digitek @ (Digoxin), he suffered bodily injury, including visual changes, palpitations, irregular pulse, cold sweats and digitalis toxicity, as well as other damages, including his death.
- 27. Defendants' conduct in the design, testing, manufacturing, advertising, marketing, promotion, labeling, warnings given and sale of Digitek @ (Digoxin) for use by the public with twice the approved level of active ingredient was a proximate cause of Richard L. Suverison's bodily injury, damages and death.
- 28. Defendants knew or, in the exercise of reasonable care, should have known that their drug was defective and that Richard L. Suverison would reasonably be expected to use their drug and suffer injury and death as a result of normal use of the drug.

- 29. Defendants owed a duty to Richard L. Suverison to design, manufacture, test, advertise, promote, sell and distribute Digitek@ (Digoxin) without hidden and concealed defects.
- 30. Defendants breached said duty to Richard L. Suverison, and thereby proximately caused his injuries, damages and death.

COUNT I STRICT LIABILITY IN TORT

- 31. The Plaintiff realleges and incorporates by reference each and every allegation contained in paragraphs one through thirty of this Complaint, and further alleges as follows:
- 32. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed Digitek@ (Digoxin) which was used and ingested by Richard L. Suverison.
- 33. Digitek @ (Digoxin) was expected to, and did, reach the usual consumers, handlers and persons coming into contact with said drug without substantial change in the condition in which it was produced, manufactured, tested, sold, distributed and marketed by Defendants.
- 34. At all times relevant to this Complaint, Digitek @ (Digoxin) was in an unsafe, defective, and inherently dangerous condition which was unreasonably dangerous to its users, specifically including Richard L. Suverison, because it contained excess levels of active ingredient.

- 35. Digitek @ (Digoxin) was so defective in design, formulation, manufacture and testing that when it left the hands of Defendants, the foreseeable risks exceeded the benefits associated with the design, formulation and manufacture of Digitek @ (Digoxin).
- 36. Defendants knew, or should have known, at all times relevant herein that Digitek @ (Digoxin) was in a defective condition and was inherently dangerous and unsafe because it contained excess levels of active ingredient.
- 37. Richard L. Suverison used Digitek @ (Digoxin) for the purpose and manner normally intended for the drug.
- 38. Richard L. Suverison, acting as a reasonably prudent person, could not have discovered that Digitek @ (Digoxin) was defective, nor could he have perceived its danger.
- 39. Defendants had a duty to create a product that was safe for its normal, intended use.
- 40. Upon information and belief, sales, prescription, use and ingestion continued after Defendants knew, or should have known, that their product contained excess levels of active ingredient and, therefore, presented risk of serious side effects including, but not limited to, nausea, vomiting, dizziness, low blood pressure, cardiac instability, bradycardia, toxicity and death, as well as other severe and permanent health consequences. Therefore,

Defendants are strictly liable in tort for the bodily injuries, damages and death of Richard L. Suverison.

- 41. The Digitek @ (Digoxin) designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants contained excess levels of active ingredient and was, therefore, unreasonably dangerous, not reasonably safe, and did not meet reasonable consumer expectations because of design and manufacturing defects, use defects including inadequate warnings, and defects attributable to inadequate testing. Defendants are, therefore, strictly liable for the injuries, damages and death of Richard L. Suverison.
- 42. The Digitek @ (Digoxin) designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants contained excess levels of active ingredient and, therefore, was defective due to inadequate post-marketing surveillance and/or warnings. Defendants are, therefore, strictly liable for the injuries, damages and death of Richard L. Suverison.
- 43. The Digitek @ (Digoxin) designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants was unreasonably dangerous because:
 - a. the manufacturing processes for the drug did not satisfy the Food and Drug Administration's manufacturing standard;
 - b. the failure of the defendants' manufacturing process for the drug to satisfy the Food and Drug Administration's applicable manufacturing standards

- resulted in unreasonably dangerous manufacturing defects; and
- c. the defendants failed to warn of the unreasonable risks created by these manufacturing defects.

COUNT II NEGLIGENCE

- 44. The Plaintiff realleges and incorporates by reference each and every allegation contained in paragraphs one through forty-three of this Complaint, and further alleges as follows:
- 45. Defendants had a duty to exercise reasonable care in manufacturing, marketing, researching, testing, design, promotion, packaging, sale and distribution of Digitek @ (Digoxin) for public consumption.
- 46. Defendants failed to exercise reasonable care and were negligent through the following acts and omissions:
 - a. Manufacturing, designing, promoting, formulating, creating, marketing, packaging, distributing and selling Digitek @ (Digoxin) in violation of FDA drug approved requirements because the drug was released for public consumption with excess levels of active ingredient beyond that approved by the FDA;
 - b. Manufacturing, designing, producing, promoting, formulating, creating, marketing, distributing and selling Digitek @ (Digoxin) without properly testing it to ensure it did not have excess levels of active ingredient;
 - c. Manufacturing, designing, producing, promoting, formulating, creating, marketing, distributing and selling Digitek @ (Digoxin) in a manner that was dangerous to intended users because it contained excess levels of active ingredient;

- d. Failing to adequately warn, timely recall or otherwise notify health care providers and users at the earliest date that it became known that Digitek @ (Digoxin) was dangerous and defective because it contained excess levels of active ingredient;
- e. Negligently advertising and recommending the use of Digitek @ (Digoxin) without ensuring the safety of the drug for its intended use;
- f. Failing to reliably establish the identity, strength, quality and purity of the Digitek @ Digoxin that Defendants released into the market; and
- g. Failing to conduct adequate post-marketing surveillance to ensure the safety of Digitek @ Digoxin.
- 47. Defendants under-reported, underestimated and/or downplayed the serious dangers and the defective nature of Digitek@ (Digoxin).
- 48. Defendants knew, or should have known, that consumers such as Richard L. Suverison would foreseeably suffer injury, including death, as a result of Defendants' failure to exercise ordinary care as outlined above.
- 49. Defendants' negligence was a proximate cause of Richard L. Suverison's bodily injuries, damages and death.
- 50. The Defendants were negligent in manufacturing Digitek@ (Digoxin) because:
 - a. their manufacturing process for the drug did not satisfy the Food and Drug Administration's manufacturing standards;
 - b. the failure of the manufacturing processes for the drug to satisfy the Food and Drug Administration's

- manufacturing standards for the devices resulted in unreasonably dangerous manufacturing defects; and
- c. the Defendants failed to warn of the unreasonable risks created by these manufacturing defects.

COUNT III BREACH OF IMPLIED WARRANTY

- 51. The Plaintiff realleges and incorporates by reference each and every allegation contained in paragraphs one through fifty of this Complaint, and further allege as follows:
- 52. Florida law imposes a duty on the seller of a product to warrant that a product is reasonably fit for its intended purpose.
- 53. Defendants, as sellers of Digitek @ (Digoxin), warranted that the drug was safe for its intended purpose, including the treatment of atrial fibrillation, atrial flutter and heart failure patients who remain symptomatic after attempts at other treatment.
- 54. Richard L. Suverison reasonably relied on the belief that Digitek @ (Digoxin) was reasonably safe and fit for its intended purpose.
- 55. Defendants breached their implied warranty because the Digitek @ (Digoxin) released for public consumption contained twice the amount of active ingredient and was not safe and fit for its intended purpose.

56. Defendants' breach of their implied warranty was a proximate cause of Richard L. Suverison's bodily injuries, damages and death.

COUNT IV BREACH OF EXPRESS WARRANTY

- 57. The Plaintiff realleges and incorporates by reference each and every allegation contained in paragraphs one through fifty-six of this Complaint, and further allege as follows:
- 58. Defendants expressly warranted that Digitek @ (Digoxin) would be reasonably safe and fit for its intended purpose.
- 59. Richard L. Suverison reasonably relied on the express warranty of Defendants that Digitek @ (Digoxin) was reasonably safe and fit for its intended use.
- 60. Digitek @ (Digoxin) does not conform to the express warranties by Defendant because the drug, as produced for public consumption, is defective and presents a high risk for injury and death to its intended users.
- 61. Defendants breached their express warranty regarding the safety and fitness of Digitek @ (Digoxin).
- 62. Defendants' breach of their express warranty was a proximate cause of Richard L. Suverison's bodily injuries, damages and death.

COUNT V PUNITIVE DAMAGE CLAIM

- 63. The Plaintiff realleges and incorporates by reference each and every allegation contained in paragraphs one through sixty-two of this Complaint, and further allege as follows:
- 64. Defendants' pattern and practice of permitting adulterated drug products to be released for consumer use; failing to reliably establish the identity, strength, quality and purity of drug products that they manufacture and release onto the market; and failure to investigate and document out-of-specification test results, constitutes an irresponsible, wanton and reckless attitude toward the safety and health of the public, including Richard L. Suverison. Such conduct was willful, deliberate, intentional, reckless, and/or malicious and was a proximate cause of Richard L. Suverison's bodily injuries, damages and death.
- 65. Defendants' concealment of the dangers presented to the public, including Richard L. Suverison, after it knew that Digitek@ (Digoxin) had been released to the general public with twice the levels of active ingredient was willful, deliberate, intentional, reckless, and/or malicious and was a proximate cause of Richard L. Suverison's injuries, damages and death.
- 66. Defendants' failure to timely and effectively notify the public, including Richard L. Suverison, that Digitek @ (Digoxin) had been released to the general public with twice the levels of

active ingredient was willful, deliberate, intentional, reckless, and/or malicious and was a proximate cause of Richard L. Suverison's bodily injuries, damages and death.

67. Plaintiff is entitled to an award of punitive damages as a result of the deliberate, willful, intentional, reckless and/or malicious conduct of Defendants outlined herein.

DAMAGES

- 68. The Plaintiff realleges an incorporates by reference each and every allegation contained in paragraphs one through sixty-seven of this Complaint, and further allege as follows:
- 69. As a direct and proximate result of the negligence, carelessness, recklessness, willful, intentional, deliberate and/or malicious acts of Defendants, individually and collectively, both jointly and severally, Richard L. Suverison suffered, prior to his death, permanent bodily injury including, but not limited to, visual changes, palpitations, irregular pulse, cold sweats and digitalis toxicity, as well as other damages requiring medical treatment and care. Plaintiff has incurred medical bills. Plaintiff has further suffered tremendous pain, suffering, loss of enjoyment of life, mental anguish and annoyance and inconvenience. Further, the foregoing was the direct and proximate cause of the death of Richard L. Suverison.

Plaintiff further seeks all other damages allowable by law,

including:

- a. The loss of the decedent's companionship And protection and for mental pain and suffering From the initial date of injury;
- b. Medical and funeral expenses of the decedent;
- c. The net accumulation of decedent's estate, Reduced to present value;
- d. Loss of support for Richard L. Suverison, Jr.

WHEREFORE, the Plaintiff, LINDA K. SUVERISON, demands judgment of and from the Defendants, both jointly and severally, in such sums as will adequately compensate the Plaintiff and punish the Defendants for the bodily injuries, damages inflicted as aforesaid and death of Richard L. Suverison, which said sums are far in excess of any sums necessary to confer the jurisdiction of the court, together with prejudgment and post-judgment interests, the costs expended in the prosecution of this lawsuit, including reasonable attorney fees, return or refund of all costs associated with the purchase of defective Digitek @ (Digoxin), disgorgement of Defendants' profits from the sale of Digitek @ (Digoxin), and do further pray for such other and further general relief as the court may deem proper.

THE PLAINTIFF FURTHER DEMANDS A TRIAL BY JURY.

LINDA K. SUVERISON

By Counse

David A. Hoines

Florida Bar Number: 195867

Hoines, Hess & Rose

3081 E. Commercial Blvd., #200 Fort Lauderdale, FL 33308-4359

Telephone: 954-772-2444 Facsimile: 954-772-1860

Counsel for Plaintiff

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% JS 44 (Rev. 2/08)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as requible local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Cothe civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

NOTICE: Attorneys MUST Indicate All Re-filed Case

Oct 27, 2009

STEVEN M. LARIMORE CLERK U.S. DIST. CT. S.D. OF FLA. · MIAMI

I. (a) PLAINTIFFS	DEFENDANTS	
Linda K. Suverison, individually and as personal representative of the Estate of Richard L. Suverison, Sr. (b) County of Residence of First Listed Plainting (EXCEPT IN U.S. PLAIN)	Mylan Pharmacel Mylan Bertek Pha County of Residence	
(c) Attorney's (Firm Name, Address, and Telephone Number) David A. Hoines, Esq., Hoines, Hess & Rose,	NOTE: IN LAN LAND	
ONLE Commercial Dlvd. Suite 200	Attorneys (If Known)	

the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

Mylan Pharmaceuticals, Inc., a West Virginia corporation, t/k/a Mylan Bertek Pharmaceuticals, Inc; Actavis Totowa, LLC; Actavis County of Residence of First Listed Defendant Monongalia (IN U.S. PLAINTIFF CASES ONLY)

(c) Attorney's (Firm Name, Address, and Telephone Number)				1	NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT LAND INVOLVED.		
David A. Hoines, Esq., Ho 3081 E. Commercial Blvd. Fort Lauderdale, FL 3330	, Suit	e 200,	4	Attorneys (If Known)	-		
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CONTRACT 110 Insurance 120 Marine 130 Miller Act 140 Negotiable Instrument 150 Recovery of Overpayment & Enforcement of Judgment 151 Medicare Act 152 Recovery of Defaulted Student Loans (Excl. Veterans) 153 Recovery of Overpayment of Veteran's Benefits 190 Other Contract 195 Contract Product Liability 196 Franchise REAL PROPERTY 1210 Land Condemnation 1220 Foreclosure 1230 Rent Lease & Ejectment 1240 Torts to Land 1245 Tort Product Liability 1290 All Other Real Property	310 315 1 320 9 330 330 345 1 340 345 1 340 3444 3 442 444 445 Employee 4446 Othorson	Airplane Product Liability Assault, Libel & Slander Federal Employers' Liability Marine Marine Product Liability Motor Vehicle Motor Vehicle Product Liability Other Personal njury IVIL RIGHTS Voting Employment Housing' ommodations Welfare Amer. w/Disabilities Lighter Amer. w/Disabilities	PERSONAL INJURY 362 Personal Injury - Med. Malpractice 365 Personal Injury - Product Liability 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY 370 Other Fraud 371 Truth in Lending 380 Other Personal Property Damage 385 Property Damage Product Liability PRISONER PETITIONS 510 Motions to Vacate Sentence Habeas Corpus: 530 General 535 Death Penalty 540 Mandamus & Other 550 Civil Rights	☐ 690 Other LABOR ☐ 710 Fair Labor Standards Act ☐ 720 Labor/Mgmt. Relations ☐ 730 Labor/Mgmt. Reporting & Disclosure Act ☐ 740 Railway Labor Act ☐ 790 Other Labor Litigation ☐ 791 Empl. Ret. Inc. Security Act	BANKRUPTCY 3 422 Appeal 28 USC 158 423 Withdrawal 28 USC 157 PROPERTY RIGHTS \$20 Copyrights \$30 Patent \$40 Trademark SOCIAL SECURITY \$61 HIA (1395ff) \$62 Black Lung (923) \$63 DIWC/DIW W (405(g)) \$64 SSID Title XVI \$65 RSI (405(g)) FEDERAL TAX SUITS \$70 Taxes (U.S. Plaintiff or Defendant) \$71 IRS - Third Party 26 USC 7609	OTHER STATUTES 400 State Reapportionment 410 Antitrust 430 Banks and Banking 450 Commerce 460 Deportation 470 Racketeer Influenced and Corrupt Organizations 480 Consumer Credit 490 Cable/Sat TV 810 Selective Service 850 Securities/Commodities/ Exchange 12 USC 3410 890 Other Statutory Actions 891 Agricultural Acts 892 Economic Stabilization Act 893 Environmental Matters 894 Energy Allocation Act 895 Freedom of Information Act 900 Appeal of Fee Determination Under Equal Access to Justice	
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VI. RELATED/RE-FILED (See instructions second page): a) Re-filed Case JUDGE		a) Re-filed Case □ YI JUDGE	ES 🗇 NO b) Relat	ed Cases			
VIII. CAUSE OF ACTI	ON 2	ite the U.S. Civil Statu iversity): 28 USC 1332(a) ENGTH OF TRIAL vi	a <u>10</u> days estimated	filing and Write a Brief Stateme I (for both sides to try entire cas DEMAND \$	c)	sdictional statutes unless vif demanded in complaint:	
ABOVE INFORMATION IS THE BEST OF MY KNOWL		/		ORNEW OF RECORD	JURY DEMAND DATE FICE USE ONLY	: XYes No 10-22-09	
				AMOUNT	RECEIPT #	124488 IFP	